510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name: Kamabry, Inc.

Company Address: 42 Colonial Lane
Bellport, NY 11713

Telephone: 631-803-6800
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OCT 0 4 2013

Contact Person: Caryn Horsley
Summary Preparation Date: July 16, 2013

DEVICE NAME **807.92(a)(2)**

Trade Name:	Inner Peace™
Common/Usual Name:	Pelvic floor exerciser
Classification Name:	Perineometer
Regulation Number:	21 CFR 884.1425
Product Code:	HIR
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	***Product***	***510(k) #***
Naissance Holdings L.C.	GyneFlex	021115
Colonial Medical Supply	Pelvic Muscle Therapy	002830
KegelMaster 2000 Ltd	Kegelmaster	K023305

DEVICE DESCRIPTION **807.92(a)(4)**

Inner Peace™ is a one-piece, silicone intravaginal pelvic-floor exercise device that squeezes down to be easily inserted, only to spring back to its original shape to fit comfortably and snugly against the vaginal walls. The enclosed spring provides resistance as the User performs kegel exercises to strengthen and tone the pelvic floor muscles

DEVICE INTENDED USE **807.92(a)(5)**

The **Inner Peace™** pelvic exercise device is recommended for the strengthening of perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence in women.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Device	Subject Device Inner Peace	Predicate Device Gyneflex	Predicate Device Pelvic Muscle Therapy	Predicate device Kegelmaster
Manufacturer	Kamabry, Inc.	Naissance Holdings, LLC	Colonial Medical Supply	KegelMaster 2000 Ltd
K Number		K021115	K002830	K023305
Common or Usual Name	Pelvic Muscle Exerciser	Pelvic Muscle Exerciser	Pelvic Muscle Exercised	Pelvic Muscle Exercised
Regulation Number	884.1425	884.1425	884.1425	884.1425
Product Code	85 HIR	85 HIR	85 HIR	85 HIR
Indications for Use	The Inner Peace™ Exercise Device is intended to assist women in performing Kegel Exercises by offering resistance, which may help control urinary incontinence.	The Gyneflex Exercise Device is intended to assist women in performing Kegel Exercises by offering resistance, which may help control urinary incontinence.	Pelvic muscle trainer assists the user to perform Kegel exercises, by offering resistance, which may help in the treatment of urinary incontinence.	The Kegelmaster 2000 is intended to assist women in performing Kegel Exercises, which may help to control stress incontinence.
OTC	Yes	Yes	yes	yes
Feature	Resistive vaginal exerciser	Resistive vaginal exerciser	Resistive vaginal exerciser	Resistive vaginal exerciser
Target Population	Women with mild incontinence	Women with mild incontinence	Women with mild incontinence	Women with mild incontinence
Anatomical Site	Vagina	Vagina	Vagina	Vagina
Single Patient device	Yes	Yes	Yes	Yes
Reusable	Yes	Yes	Yes	Yes
Sterile	Clean, but not sterile	Clean, but not sterile	Clean, but not sterile	Clean, but not sterile
Biofeedback display information	no	no	Numerical response to muscle contraction strength	no

Material Design	One-piece, silicone overmold with attached string and with an embedded spring inside unit.	V shaped Polymer plastic	Handheld pneumatically based device with vaginal silicone sensor	Plastic and stainless steel spring progressive resistance pelvic exerciser
Material	polydimethysiloxane	Polymer plastic	polydimethysiloxane	Plastic and stainless steel springs
Operating Principle	Resistive pelvic floor strengthener	Resistive pelvic floor strengthener	Resistive pelvic floor strengthener	Resistive pelvic floor strengthener
Resistive component	Embedded spring	V- shape in 6 graduated ranges of resistance	Balloon silicone sensor	Stainless steel springs
Biocompatibility	Guidelines set forth in ISO 100993 testing results indicated material is biocompatible, nontoxic and well tolerated by mucosal membranes	Guidelines set forth in ISO 100993 testing results indicated material is biocompatible, nontoxic and well tolerated by mucosal membranes	Guidelines set forth in ISO 100993 testing results indicated material is biocompatible, nontoxic and well tolerated by mucosal membranes	Guidelines set forth in ISO 100993 testing results indicated material is biocompatible, nontoxic and well tolerated by mucosal membranes
Instructions for use	Manual	Manual	Manual	Manual
Packaging	Device in sealed plastic bag and manual in cardboard box	Device in sealed plastic bag and manual in cardboard box	Sensors in sealed plastic bag, Monitor, Video, manual in cardboard box	

NON-CLINICAL PERFORMANCE DATA **807.92(b)(1)**

BIOCOMPATIBILITY
The Inner Peace™ was tested in accordance with the testing requirements of the ISO 10993 Recognized Standards and found to be safe for its intended use.

PERFORMANCE TESTING
Various mechanical tests were performed to establish safe use.

CONCLUSION **807.92(b)(3)**

The Inner Peace™ pelvic exerciser is similar to the predicate devices in:

- Indications for Use
- Operating Principle
- Materials

After analyzing Biocompatibility results, performance bench testing and colorant studies, Kamabry, Inc. has concluded that Inner Peace™ pelvic exerciser is substantially equivalent to the predicate devices and introduces no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

Kamabry, Inc.
% Yolanda Smith
Regulatory Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K122800
Trade/Device Name: Inner Peace™
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: September 24, 2013
Received: September 25, 2013

Dear Yolanda Smith.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122800

Device Name: Inner Peace™

Indications for Use:

The **Inner Peace™** pelvic exercise device is recommended for the strengthening of perineal pelvic floor muscles by offering resistance to an individual's voluntary contractions of these muscles. It seeks to correct, through exercise, urinary incontinence in women.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___✓___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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